510(k) Summary

Trade Name: **Vision-Sciences Flexible Fiberoptic Bronchoscope and EndoSheath® System**

Sponsor: Vision-Sciences, Inc.
9 Strathmore Road
Natick, MA 01760
Registration #1223490

Device Generic Name: Flexible, fiberoptic bronchoscope with protective sheath system

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Devices: **K963795 – Bronchoscope with Disposable EndoSheath®**
K990354 – Modified EndoSheath® for Flexible ENT Scopes

Manufactured by:
Vision-Sciences, Inc.
9 Strathmore Road
Natick, MA 01760

Product Description: The device system described in this 510(k) consists of a modified sterile, disposable sheath designed to fit the modified VSI flexible fiberoptic bronchoscope. The use of an EndoSheath® eliminates the need for high-level disinfection of the scope following each procedure. The sheath and scope have been modified to accommodate the "slide-on" sheath installation technique.

Indications for Use:
The Bronchoscope with EndoSheath® System is used for flexible endoscopic examination of the trachea and other major passages of the lungs, to gather specimens, and/or to find and endoscopically remove foreign objects from the lungs.

Safety and Performance:
This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Vision-Sciences has provided certification of compliance to 21 CFR 820.30 Design Control requirements, and a description of the internal Risk Analysis procedure. Validation testing including microbial barrier testing, sheath tensile/elongation testing, sheath leak testing, sheathed scope articulation testing and sheathed scope image quality evaluation is included in Design Validation and Verification planning.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to predicate devices, the modified VSI Flexible Fiberoptic Bronchoscope and EndoSheath® System has been shown to be safe and effective for its intended use.

Table D.1
Design Comparison

Characteristic	Proposed Modified Bronchoscope with Slide-on EndoSheath® System (Current Submission)	Currently Marketed, Unmodified Bronchoscope with EndoSheath® System (K963795)	Currently Marketed Slide-on EndoSheath® System for use with ENT Scopes (K990354)	Currently Marketed VSI Flexible GI Scope/EndoSheath® Systems*	Substantial Equivalence Comparison: Proposed Modified Bronchoscope with Slide-on EndoSheath® System
Up/Down Articulation (sheathed scope)	170°/120°	170°/120°	No S.E. comparison required – different intended use		Equivalent to unmodified VSI Bronchoscope/sheath system
Field of View	90°	90°			Identical to unmodified VSI Bronchoscope/sheath system
Diopter	+2/-8	+2/-8			
Depth of Field	3 – 50 mm	3 – 50 mm			
Insertion Tube OD	6.0 mm	6.0 mm			
Working Channel ID	2.1 mm	2.1 mm			
Working Length	550 mm	550 mm			
Immersible scope	Yes	Yes	Yes	Yes	
Microbial barrier claim	Yes	Yes	Yes	Yes	
Mating scope models	VSI Bronchoscope	VSI Bronchoscope	Various	VSI GI Scopes	
Sheath installation method	Slide-on	Vacuum	Slide-on	Pressure	Identical to VSI ENT Scope/sheath system
Sheath wall thickness	.0020 - .0045"	.010 ± .002"	.0020 - .0045"	No S.E. comparison required – different sheath material	Identical to VSI ENT Scope/sheath system

* Currently marketed Vision-Sciences GI Endoscope/EndoSheath Systems:

K963344; Flexible Fiberoptic Sigmoidoscope with EndoSheath® System (Sig)
K943715; Flexible Fiberoptic Gastroscope with EndoSheath® System (Gastro)
K943895; Flexible Fiberoptic Colonoscope with EndoSheath® System (Colo)

Table D.3
Product Changes/Testing Summary

Change Description	Where/How Evaluated (V&V Tests)
Sheath material changed	• Sheath burst/leak test • Sheath tensile/elongation test • Sheath installation/system functional test • Microbial barrier test
Sheath working channel construction changed	• Sheath burst/leak test • Sheath tensile/elongation test • Sheath installation/system functional test • Microbial barrier test
Suction valve moved from sheath to scope	• Sheath installation/system functional test • Pinch valve cycle test

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 4 2002

Vision Sciences, Inc.
C/O Delphi Medical Device Consulting
5 Whitcomb Avenue
Ayer, MA 01432
Attn: Ms. Pam Papineau

Re: K021344
Trade/Device Name: B-F200 Bronchoscope with BSS-F21 Endosheath System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: April 24, 2002
Received: April 29, 2002

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K021344

Device Name: Flexible Fiberoptic Bronchoscope with EndoSheath® System

Indications for Use:

The VSI Flexible, Fiberoptic Bronchoscope with EndoSheath® System is used during flexible endoscopic examination of the trachea and other major passages of the lungs, to gather specimens, and/or to find and endoscopically remove foreign objects from the lungs. The EndoSheath® provides a sterile, disposable protective covering for the bronchoscope.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K021344